

U.S. CONSUMER PRODUCT SAFETY COMMISSION WASHINGTON, D.C. 20207

MINUTES OF COMMISSION MEETING May 30, 2001 4330 East West Highway Bethesda, Maryland

Chairman Ann Brown convened the May 30, 2001, meeting of the U. S. Consumer Product Safety Commission in open session. Commissioner Mary Sheila Gall and Commissioner Thomas H. Moore were present.

Agenda Item: Baby Bath Seats Petition HP 00-4

The Commission considered options regarding Petition HP 00-4, filed by the Consumer Federation of America and nine other organizations, requesting that the Commission ban baby bath seats to address a risk of injury or death by drowning. The Commission was briefed on this matter by the staff at the Commission meeting of May 23, 2001. (Ref: staff briefing package dated March 30, 2001.) The Commission also received supplemental information from the staff responding to questions raised by Commissioner Gall.

On motion of Chairman Brown, the Commission voted unanimously (3-0) to grant petition HP 00-4 concerning baby bath seats and to approve and publish in the <u>Federal Register</u> the draft advance notice of proposed rulemaking (ANPR) currently before the Commission, subject to revisions still to be made and decided upon by the Commissioners. The <u>Federal Register</u> notice will be sent around by ballot to accomplish revisions Commissioners desire to make and to give time for staff to make technical changes as needed.

Chairman Brown, Commissioner Gall, and Commissioner Moore filed separate statements concerning the baby bath seat matter, copies attached.

There being no further business on the agenda, Chairman Brown adjourned the meeting.

For the Commission:

Sadye E. Dunn

Secretary to the Commission

Attachments

STATEMENT OF CHAIRMAN ANN BROWN IN FAVOR OF GRANTING THE PETITION AND ISSUING AN ADVANCE NOTICE OF PROPOSED RULEMAKING ON BABY BATH SEATS

May 30, 2001

Today, I voted to grant a petition submitted by the Consumer Federation of America and nine other consumer groups on baby bath seats and to begin a rulemaking proceeding by publishing an advance notice of proposed rulemaking (ANPR) in the Federal Register. We have the authority and responsibility to take action against consumer products – like baby bath seats – that are contributing to the death of babies. That is what Congress created us to do; that is what the public expects of us; that is what we must do. It is our mission.

Baby bath seats are contributing to babies' deaths. Seventy-eight babies have died in this silent and gruesome way. I am haunted by the fact that sixty-five babies have died since the majority of the Commission voted against an ANPR in 1994.

The caregiver, with a false sense of security as a result of the bath seat, leaves the child unattended or turns away and the bath seat fails in some way – the seat tips over, the child comes out of the seat, the child becomes entrapped in the leg opening, or the child slumps over. The labels on the product warn against using them on non-skid surfaces, even though the vast majority of bathtubs sold today have non-skid surfaces.

Manufacturers can see the danger. Once there were ten manufacturers. Now one company – Safety First – has 99% of the market. Fisher Price told us that they got out of the business because "the product itself, during normal use, seemed to imply that supervision was not necessary . . . The risks to consumers were not warranted." That speaks volumes.

The behavior of the parents or caregivers is not what is at issue. Our statutes are talking about dangerous products, not who pays for the victim's injury or who is to blame. The statute says a product presents a mechanical hazard if, "in its normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness."

The ANPR I voted for today will give us the opportunity to continue to collect more information on this issue, explore solutions, and encourage innovation. We have had a string of technical breakthroughs to marvel at – the internet, fiber optics, biotechnology, and in our own universe, baby walkers that automatically stop at the edge of the steps. I hope our ANPR for baby bath seats will generate the kind of burst of creative energy we saw with baby walkers, where we and industry came up with an innovative and effective technical solution.

These babies deserve our protection. No matter how you may feel about the parent's behavior, it is the children dying, not the parent. These deaths are foreseeable and can be prevented. Products for infants need to be designed with the assumption that parents will not always be 100% attentive to their children. That inattention is entirely foreseeable and needs to be accounted for. Death should not be the result of a parent being absent for a moment. If children can be saved by designing the hazards out of bath seats, we must try to save them. We can do no less.

Our action here should be based on more than economic, policy, or political considerations. This is about our values. We cannot realistically save every life, but our actions should show that every life matters.



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STATEMENT OF THE HONORABLE THOMAS H. MOORE ON THE PETITION ON BABY BATH SEATS

May 30, 2001

Since its inception, the Commission has been grappling with how to solve the problem of children drowning, or being put at risk of drowning, in bathtubs. In 1974 the agency commissioned a study to devise a program to reduce the incidence and severity of bathtub injuries, including drownings. Even then, well over 90% of the drowning incidents occurred when the child was left unattended. While the study concluded that drownings are best addressed through educating the parent or user not to leave children alone in the tub, it did make recommendations as to product accessories that could reduce bathtub drownings. The first such accessory recommended in the study was the bath seat. Since that study was done, baby bath seats have become a part of many American families' lives.

Over twenty-five years ago, some safety experts were looking at baby bath seats as a drowning solution. Now we are looking at them as part of the problem. In 1994 the Commission decided not to proceed with a rulemaking on baby bath seats and the majority of the Commissioners concluded that baby bath seats were not a mechanical hazard under the Federal Hazardous Substances Act. Having looked at the death scenarios with which the Commission was faced, I can see that it would have been more difficult to make the case back in 1994 that baby bath seats presented a mechanical hazard. Data was limited, there were fewer cases and a number of those cases presented unusual circumstances that raised questions about the incident scenarios.

Since then we have gotten enough additional detailed incidents, that even when one weeds out the questionable cases, a sufficient number remain to allow the identification of likely product design problems which might present an unreasonable risk of harm. Because we lack information about how caregivers actually use baby bath seats and have to rely on baby bath seat ownership data when making risk calculations, it is difficult to say with any certainty what baby bath seats, as a product category, have contributed in either a positive or a negative fashion to bathtub safety. However, it does appear that changes can be made to these products that will reduce the incidence of certain drowning scenarios that involve baby bath seats. And that is enough to issue an Advance Notice of Proposed Rulemaking. I view an Advance Notice of Proposed Rulemaking as a fact-finding mechanism. It allows us to hone the issues and refine our knowledge. How the Commission then proceeds is shaped in large part by the information developed during this stage.

One thing is clear with regard to bathtub drownings-- we cannot save every child. There are cases where so many complicating factors contributed to the child's death (and with contradictory information as to what really happened) that they are difficult to analyze in injury

prevention terms. We will never know with any certainty what happened in some of these cases. Therefore, when the briefing package talks about baby bath seats being involved in approximately 8 deaths a year, that is somewhat of a misleading number both as to defining the scope of the problem and as to our ability to solve it. But there do seem to be ways to improve the safety of baby bath seats. The incident reports indicate that relying on suction cups for stability is no longer a viable solution, particularly as fewer and fewer tubs have the pristinely smooth surface required for their proper use. The size of the leg hole openings needs to be examined and perhaps made smaller to protect an infant from slipping both legs through one leg hole and becoming entrapped. Indentations on the ring encircling the child that can accumulate water and present a separate drowning hazard, need to be eliminated.

I also believe that the amount of water in which the product is placed needs to be addressed in some fashion. Whether a water line on the product could be helpful will depend upon what types of products we end up with at the end of this process. If one looks at the depth of the water in many of the in-depth investigations, it is clear to me that overly deep water contributed to the deaths of a number of the children, either by floating them out of the seat or by being so high the children could not continue to hold their heads out of the water. Certainly an aggressive on-going information and education campaign, which I believe the Commission should undertake in the area of bathtub drownings, should emphasize the importance of using as little water as possible. This may solve part of the "retention" problem identified by staff.

We do need to be careful, however, about mandating design solutions to certain other aspects of the retention issue. I am not sure that strapping a child in these devices in water is necessarily a good thing, since we believe certain caregivers will be encouraged by this to leave their children alone for even longer amounts of time. If possible I would like to see the product design reinforce the notion that children can never be left unattended in water. On the other hand, I would not want to eliminate categorically any possible solution at this point. There may be a restraint system that solves the problem without presenting another one.

While we would never rely solely on warning labels to prevent infant drownings, we may want to take another look at how to more graphically remind older caregivers (and educate very young, less experienced ones) about the dangers of babies and water. And we should also examine whether a more prominent placement on the product of these graphic warnings would reinforce that message.

Therefore, today I am voting to grant the baby bath seat petition and, subject to revisions still to be made and decided upon by the Commissioners to the draft ANPR, to approve the issuing of an Advance Notice of Proposed Rulemaking.

I hope the baby bath seat manufacturers and other interested parties will work with our staff to come up with creative solutions to these problems. Pooling our resources, talent and creativity should yield a product that continues to provide the benefits many consumers derive from this product while eliminating the addressable hazards that are created by the foreseeable actions of well-meaning but misguided caregivers. The ANPR process will have the salutary effect of keeping this issue in the public eye and on the front burner at the Commission. That, in turn, will give us opportunities to get the message out that under no circumstances can babies be left alone in a tub, or left with older siblings who are still being bathed themselves. If that message could become ingrained in our child-rearing philosophy, it would eliminate nearly all of these deaths.



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STATEMENT OF THE HONORABLE MARY SHEILA GALL IN FAVOR OF ISSUANCE OF ADVANCE NOTICE OF PROPOSED RULEMAKING ON BABY BATH SEATS

May 30, 2001

Today I am voting in favor of an Advance Notice of Proposed Rulemaking (ANPR) for baby bath seats. The proposed rule should address the stability/retention problem and the dimensions of the leg hole openings, designed to reduce the incidents in which infants tip over in bath seats or in which infants slide through the leg hole openings and become entrapped. I believe that the Commission should vote on the specific language of the Federal Register notice by ballot.

A Rule Containing A Performance Standard May Be Appropriate

The evidence presented to the Commission at last week's briefing revealed a very different picture about baby bath seats than was the case in 1994. The staff has collected 106 "near miss" incidents, 40 of which illustrate the hazards that bath seats can present *even when* a caregiver is present. In addition, the staff has several technical concepts to address the stability/retention problem, as well as the problem of leg hole openings.

The Federal Hazardous Substances Act (FHSA), and my own regulatory philosophy, mandate deferral to voluntary standards whenever the standard is adequate and it is likely that there will be substantial compliance with it. There is a voluntary standard for baby bath seats. It seeks to deal with the problem of suction cups not adhering to non-skid bathtub surfaces through a warning label. This aspect of the voluntary standard is not adequate because the label appears on the packaging, which is likely to be discarded after the bath seat is put into use. Most tubs sold today have non-skid surfaces. A member of the general public, Mrs. Carolyn Brummel, described a "near-miss" incident of a bath seat tipover in which only the presence of the caregiver averted a tragedy. Other near-miss incidents

show that bath seats tip over too readily even when a caregiver is nearby. I believe that the Commission should proceed with an ANPR to investigate the possibility of developing a bath seat that resists tipping over on both non-skid and traditional bathtub surfaces.

In addition to "near-miss" incidents involving tipovers, we also see "near-misses" in the presence of caregivers in which infants slip through the leg hole openings and become entrapped in the bath seat ("submarining"). The voluntary standard does not address the dimensions of the leg hole openings. A task group of the voluntary standards subcommittee considering bath seats is presently considering this aspect of bath seat design. The "submarining" hazard that the leg hole dimensions are designed to address has, however, been well known since at least 1994. I believe that it is appropriate for the Commission itself to consider how to address this hazard.

I hope that the voluntary standards process will not be impeded by the issuance of this ANPR. I reject Chairman Brown's assertion that an ANPR has any "magical properties." Our staff are not wizards or sorcerers, and Commissioners wield no magic wand that make product hazards disappear. Developing stability requirements and deciding upon appropriate leg hole dimensions while retaining the utility of the product will take hard work and a great deal "risk-risk" analysis. The least desirable result of any standard, mandatory or voluntary, is a bath seat that does what the petitioners here claim it does: induce caregivers to leave infants unattended in tubs.

A Ban Is Not Appropriate

The petition before the Commission requests a ban of baby bath seats. In June 1994 the staff presented the Commission with a number of regulatory options that included both a performance standard and an outright ban. Most of the discussion in 1994 focused on whether a ban was justified. I voted not to go forward with rulemaking, because the evidence in the record did not support a ban and the staff had presented little data on the feasibility of a performance standard.

The Commission staff now recommends that the Commission issue an ANPR to develop a performance standard. The briefing package does not recommend a ban. My own review of the record supports my position that baby bath seats should not be banned. I base my continued opposition to a ban on my review of the in-depth investigations (IDI's), and the lack of any credible evidence that infants bathed in bath seats are at greater risk of drowning than infants bathed without bath seats.

Millions of American consumers use this product every day without incident. A member of the general public who testified before the Commission last week, Mrs. Vienna Haak, said that she had found the bath seat to be a useful bathing aid and had never experienced a problem with it.

In-Depth Investigations (IDI's)

When I voted in 1994 not to proceed with rulemaking, I had read carefully each and every IDI describing the circumstances of an infant tub drowning where a bath seat happened to be present. My review of those IDI's revealed that infant tub drownings occurred in extreme circumstances of neglect. I believe that the presence of the bath seat was in no way causally related to the decision to leave the child unattended in the tub.

In preparation for last week's briefing I reviewed all of the IDI's on infant tub drownings in the presence of a bath seat. Sadly, there have now been seventy-eight instances in which an infant drowned in a bathtub where a bath seat was present. But the circumstances of many of those infant tub drownings remain the same egregious cases of neglect, none of which can be attributed to the presence of a bath seat. In one case, a drunken mother left an infant in a bath seat with the water running, and stayed away so long that water flowed over the tub, and flooded the bathroom floor. Water then soaked through the floor and dripped from the living room ceiling below. In other cases, older siblings left alone in the tub with infants lifted them out of the bath seats, and placed them in the tub of water. No bath seat standard, voluntary or mandatory, will make any difference in circumstances such as these.

Relative Risk Of Drowning

Staff Analysis

Both the staff briefing package and the staff's response to a letter from Dr. Kimberly Thompson, a researcher at the Harvard School of Public Health, who commented on the briefing package, conclude that infants aged 5 to 7 months are at greater risk of drowning if they are bathed with a bath seat than if they are bathed without a bath seat. I am not, however, persuaded by the staff analysis. Figures collected by the National Center for Health Statistics show that the overall numbers and the risk of infant tub drownings remained constant during the 1980's and declined during the 1990's. Ownership of baby bath seats, however, increased significantly during the 1980's and slightly during the 1990's. If the presence of

baby bath seats induced caregivers to leave infants unattended in tubs, one would naturally expect that the overall numbers of drownings and the risk of drowning would increase. That has not been the case. In addition when one examines the relative risk of drowning for infants aged 5 to 10 months, one finds that the percentage of infants who drown in the presence of bath seats is very similar to the percentages of new mothers who own bath seats. Thus, the staff analysis of the drowning data provides little support for the hypothesis that caregivers are more inclined to leave infants unattended in tubs in the presence of a bath seat.

The Study by Dr. Mann

The petition relied heavily on a study conducted by Dr. Clay Mann of the Intermountain Injury Control Research Center (the Mann Study). This study purported to show that caregivers were more likely to leave an infant unattended in the presence of a bath seat than in its absence. I find the Mann study unpersuasive for a number of reasons. First, the Mann study has never been published in a peer-reviewed journal and exists only as a series of slides in a PowerPoint presentation. Second, the Mann study is highly dependent on recollections of persons who have just been through a very traumatic event; the death of a child. Third, the Mann study had only two behavioral findings that were statistically significant: median bath water depth and the reported reason for leaving the infant unattended. In neither case is there good evidence that the behavioral difference results in any greater risk to infants in tubs

Conclusion

The evidence presented to the Commission will not a support a ban of baby bath seats. There is no evidence that infants being bathed in baby bath seats are at greater risk than drowning than infants bathed without them. Nevertheless, I am persuaded that an ANPR is appropriate in two areas, the stability/retention on non-skid surfaces and leg hole opening dimensions, because the voluntary standard is not adequate. I caution, however, that any standard, voluntary or mandatory, should not result in a product that induces caregivers to leave infants unattended in bath seats.